

DECISION OF THE EEA JOINT COMMITTEE

No 47/2012

of 30 March 2012

amending Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement

THE EEA JOINT COMMITTEE,

Having regard to the Agreement on the European Economic Area, as amended by the Protocol adjusting the Agreement on the European Economic Area, hereinafter referred to as 'the Agreement', and in particular Article 98 thereof,

Whereas:

- (1) Annex II to the Agreement was amended by Decision of the EEA Joint Committee No 10/2012 of 10 February 2012 ⁽¹⁾.
- (2) Commission Regulation (EC) No 668/2009 of 24 July 2009 implementing Regulation (EC) No 1394/2007 of the European Parliament and of the Council with regard to the evaluation and certification of quality and non-clinical data relating to advanced therapy medicinal products developed by micro, small and medium-sized enterprises ⁽²⁾ is to be incorporated into the Agreement,

HAS ADOPTED THIS DECISION:

Article 1

The following point shall be inserted after point 15zl (Commission Decision 2008/911/EC) in Chapter XIII of Annex II to the Agreement:

'15zm. **32009 R 0668**: Commission Regulation (EC) No 668/2009 of 24 July 2009 implementing Regulation

(EC) No 1394/2007 of the European Parliament and of the Council with regard to the evaluation and certification of quality and non-clinical data relating to advanced therapy medicinal products developed by micro, small and medium-sized enterprises (OJ L 194, 25.7.2009, p. 7)'.

Article 2

The text of Regulation (EC) No 668/2009 in the Icelandic and Norwegian languages, to be published in the EEA Supplement to the *Official Journal of the European Union*, shall be authentic.

Article 3

This Decision shall enter into force on 31 March 2012, provided that all the notifications under Article 103(1) of the Agreement have been made to the EEA Joint Committee (*).

Article 4

This Decision shall be published in the EEA Section of, and in the EEA Supplement to, the *Official Journal of the European Union*.

Done at Brussels, 30 March 2012.

For the EEA Joint Committee

The Acting President

Gianluca GRIPPA

⁽¹⁾ OJ L 161, 21.6.2012, p. 16.

⁽²⁾ OJ L 194, 25.7.2009, p. 7.

(*) No constitutional requirements indicated.